IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

Nidia Teran,	)	
	)	
Plaintiff,	)	
	)	
	)	
	)	
	)	
	)	
v.	)	No. 19 C 6351
	)	
Coloplast Corp.	)	
	)	
Defendant.	)	

Memorandum Opinion and Order

After the birth of her third child, plaintiff Nidia Teran sought medical treatment for pelvic pain, recurrent urinary tract infections, and incontinence. Her primary care doctor referred her to urologist Alan Sadah, who diagnosed her with Grade IV cystocele with cervical/uterine prolapse—the most severe stage of pelvic organ prolapse ("POP") characterized by herniations of the bladder and uterus. In March of 2014, Dr. Sadah performed a pelvic floor reconstructive surgery called a sacrohysteropexy using a polypropylene "Restorelle Y" surgical mesh implant—a product manufactured by defendant Coloplast—to repair her condition. But plaintiff's pelvic pain only worsened, and in June of 2015, she underwent a second surgery to remove her uterus and to explant the Restorelle Y mesh. During that procedure, a cystotomy occurred,

i.e., a surgical instrument sliced a hole in plaintiff's bladder, necessitating further surgical repairs and ultimately bladder reconstruction. Since then, plaintiff has undergone numerous additional surgeries and procedures to repair recurrent vesicovaginal fistulas and remove bladder stones, and she continues to suffer from chronic pelvic pain, urinary tract infections, urinary frequency, urgency, incontinence, bladder spasms and a need for catheterization.

On March 31, 2016, plaintiff filed this lawsuit in the multi-district litigation ("MDL") pending in the U.S. District Court for the Southern District of West Virginia, identifying eighteen counts for injuries she claims were caused by defendant's Restorelle Y surgical mesh and defendant's failure to warn her adequately of the risks associated with implantation of that product. After the case was transferred here following discovery, defendant moved for summary judgment of all of plaintiff's claims. In conjunction with that motion, defendant filed motions to exclude testimony proffered by plaintiff's experts, Drs. Ostergard, Chughtai, and Mays. Plaintiff's opposition to summary judgment is likewise accompanied by *Daubert* motions seeking to exclude the testimony of defendant's experts, Drs. Culligan, Cole, Molavi, and Becker.

For the reasons explained below, I grant defendant's summary judgment motion in part, and resolve the remaining motions as follows.

I.

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). My role at this juncture is not to "weigh the evidence and determine the truth of the matter" but rather to determine if "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Accordingly, I credit plaintiff's admissible evidence and draw all reasonable inferences in her favor. *Id.* at 255.

Expert testimony is admissible under Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrill Dow Pharmaceuticals*, 509 U.S. 579 (1993), if the expert is qualified and the testimony is reliable and relevant. In my role as gatekeeper, I must determine whether: (1) the witness is qualified in the relevant field; (2) the expert's methodology is scientifically reliable; and (3) the expert's testimony will assist the trier of fact in understanding the evidence or determining a fact in issue. *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 779 (7th Cir. 2017). Importantly, "the key to the gate is not the ultimate correctness

of the expert's conclusions. Instead, it is the soundness and care with which the expert arrived at her opinion[.]" *Schultz v. Akzo Nobel Paints,* LLC, 721 F.3d 426, 431 (7th Cir. 2013). Accordingly, my analysis does not "take the place of the jury to decide ultimate issues of credibility and accuracy." *Lapsley v. Xtek*, Inc., 689 F.3d 802, 805 (7th Cir. 2012). And because "the admissibility determination is not intended to supplant the adversarial process...even 'shaky' testimony may be admissible." *Ortiz v. City of Chicago*, 656 F.3d 523, 536 (7th Cir. 2011). *See also Walker v. Ethicon, Inc.*, No. 12-CV-1801, 2017 WL 2992301, at *2 (N.D. Ill. June 22, 2017) (if expert testimony is reliable and relevant, "the accuracy of the actual evidence is to be tested before the jury with the familiar tools of vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.").

II.

Although plaintiff's complaint asserts eighteen counts for claims sounding in products liability, fraud, breach of warranty, consumer protection, and various other theories of liability, she tacitly concedes by her silence in response to several of defendant's arguments that she lacks evidence sufficient to take certain of her claims to trial. Accordingly, I grant defendant's motion as unopposed insofar as it seeks judgment on: plaintiff's claims under consumer protection laws (Count XIII); her warranty-

based claims (Counts XI and XII); her unjust enrichment claim (Count XV); her gross negligence claim (Count XIV), her loss of consortium claim (Count XVI), and her claim captioned "Discovery Rule and Tolling" (Count XVIII).[1] What remains in dispute is whether the admissible evidence entitles plaintiff to a jury trial on her claims of negligence (Count I), strict liability-manufacturing defect (Count II), strict liability – failure to warn (Count III), strict liability – defective product (Count IV), strict liability – design defect (Count V), common law fraud (Count VI), fraudulent concealment (Count VII), constructive fraud (Count VIII), negligent misrepresentation (Count IX), negligent infliction of emotional distress (Count X), and punitive damages (Count XVII).

A. Expert Testimony - Causation

Defendant's broadest summary judgment argument is that plaintiff lacks admissible evidence that her injuries were proximately caused by her mesh implant. Under Illinois law, "proximate cause can only be established when there is a reasonable certainty that the defendant's acts caused the injury," *Wintz By & Through Wintz v. Northrop Corp.*, 110 F.3d 508, 515 (7th Cir.

[1] This count does not appear to state an independent claim but rather a theory relating to the timeliness of her remaining claims. In any event, because defendant does not raise the issue of timeliness, and nothing in plaintiff's submissions suggests that this count raises any substantive right to relief, summary judgment is appropriate.

1997) (quoting *Schultz v. Hennessy Industries*, 584 N.E.2d 235, 241 (Ill. App. Ct. 1991)), and products liability cases require expert testimony to establish causation, *Wheeler v. C.R. Bard, Inc.*, No. 19-CV-08273, 2022 WL 971394, at *4 (N.D. Ill. Mar. 31, 2022) (citation omitted).

Defendants contend that neither Dr. Ostergard nor Dr. Chughtai can testify competently that defendant's product proximately caused her injuries. Because I agree that plaintiff cannot survive summary judgment without these witnesses' causation testimony, I begin by determining whether the testimony they seek to provide satisfies the *Daubert* standard.

Donald R. Ostergard

Plaintiff has designated Dr. Ostergard to offer opinions related to injury causation and the allegedly defective design and manufacture of Restorelle Y mesh. Dr. Ostergard is a retired urogynecologist who has published hundreds of peer-reviewed articles on the topic of urogynecology and has performed thousands of pelvic organ prolapse surgeries using polypropylene mesh and other materials. He has held several academic positions in the fields of obstetrics, gynecology, and women's health, and he has been qualified to provide testimony in a number of cases in this MDL. *See, e.g., Waltman v. Bos. Sci. Corp.*, No. 2:12-CV-691, 2016 WL 3198322, at *13 (S.D.W. Va. June 8, 2016); *Tyree v. Boston Scientific*, 54 F. Supp. 3d 501, 549-53 (S.D. W. Va. 2014.).

Nevertheless, defendant contends that Dr. Ostergard is unqualified to offer the opinions set forth in his expert report because he has never performed any surgery involving the Restorelle Y mesh, has never performed a robotic-assisted sacrohysteropexy with a surgical mesh implant, and has not treated patients or performed any surgery in the past decade. But there is no serious question that Dr. Ostergard is highly qualified "by knowledge, skill, experience, training, [and] education" in the medical fields relevant to his testimony. Accordingly, the issues defendant raises are better analyzed through the lens of *Daubert*'s reliability and relevance prongs.

With respect to the first of these prongs, defendant argues that Dr. Ostergard's causation opinions are unreliable because he failed to consider likely alternative causes of plaintiff's injury. Dr. Ostergard's causation analysis proceeds through the process of differential diagnosis, which is "a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 669 (S.D.W. Va. 2014). Generally speaking, differential diagnosis (or, more accurately in this context, "differential etiology") is an "accepted and valid methodology." *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). To survive *Daubert* scrutiny, a differential etiology must reflect "scientifically valid decisions

as to which potential causes should be 'ruled in' and 'ruled out.'" *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007) (citation omitted).

In defendant's view, Dr. Ostergard failed to account adequately for likely alternative causes of plaintiff's injuries, including, most significantly, Dr. Sadah's mesh implantation procedure, which the jury in a malpractice suit plaintiff filed against him found to be negligent and to have caused plaintiff millions of dollars in damages.[2] Setting aside that Dr. Ostergard *did* consider whether Dr. Sadah performed plaintiff's mesh implantation procedure within the standard of care—his view merely differs from the jury's—plaintiff need not exclude Dr. Sadah's negligence as a cause of her injuries to prevail in her claim that she was injured by defendant's defective mesh. *See Sherer-Smith v. C.R. Bard, Inc.*, No. 19-CV-903-JDP, 2020 WL 1470962, at *4 (W.D. Wis. Mar. 26, 2020) ("[t]o be considered a 'cause,' the defect need not be the sole cause or even the primary cause; it is sufficient to show that the defect was a substantial factor in causing the injury.").[3] Moreover, Dr. Ostergard "need not testify

[2] *See* Order, *Nidia Teran v. Alan Y. Sadah, M.D., et al.*, No. 17-L-004790 (Cir. Ct. of Cook Cty. Mar. 2, 2022)(awarding plaintiff $7,535,459.76 in damages), ECF 155-3; verdict form itemizing plaintiff's damages in plaintiff's malpractice case, ECF 155-3.

[3] Although the *Sherer-Smith* court applied Wisconsin law, Illinois law similarly recognizes that injuries can have more than one proximate cause. *See Mack v. Ford Motor Co.*, 669 N.E.2d 608, 613

with complete certainty about the cause of an injury; rather he may testify that one factor could have been a contributing factor to a given outcome." *Gayton v. McCoy*, 593 F.3d 610, 619 (7th Cir. 2010). At bottom, Dr. Ostergard's testimony is sufficiently reliable if he "consider[s] alternative causes" to "show why a particular alternative explanation is not, in [his] view, the *sole* cause" of her injuries. *Schultz v. Akzo Nobel Paints*, LLC, 721 F.3d 426, 434 (7th Cir. 2013) (emphasis in original). I conclude that his report and deposition testimony satisfy this standard.

In his supplemental report, Dr. Ostergard identifies and excludes a number of potential alternative causes. Ostergard Supp. Rep., ECF 142-2 ¶¶ 84-93. While I agree that he gives many of these cursory attention, defendant will have ample opportunity to expose this weakness in his analysis through cross-examination. *See Enborg v. Ethicon, Inc.*, No. 220CV02477AWIBAK, 2022 WL 800879, at *11 (E.D. Cal. Mar. 16, 2022) (acknowledging that "many of [Dr. Ostergard's] determinations [concerning alternative causes] strike the Court as conclusory, unclear and unconvincing," but declining to exclude his testimony, reasoning that he nevertheless "proffered relevant testimony putatively based on a relevant data set" and performed a differential diagnosis, and that "whatever

(Ill. App. Ct. 1996) (citing *Bentley v. Saunemin Township*, 413 N.E.2d 1242, 1246 (Ill. 1980)).

defects there may be in Dr. Ostergard's work go to the weight of his testimony and become fodder for cross-examination."). The same goes for other potential causes that Dr. Ostergard did not discuss. *See Wheeler v. C.R. Bard, Inc.*, No. 19-CV-08273, 2022 WL 971394, at *12 (N.D. Ill. Mar. 31, 2022) (declining to bar causation witness even though she "did not mention" certain potential causes in her differential diagnosis). Indeed, Dr. Ostergard "is not required to rule out every alternative cause" of plaintiff's injuries to survive *Daubert* scrutiny. *Schultz*, 721 F.3d at 434. In short, I decline to exclude Dr. Ostergard's causation opinions on the basis that the methodology he used was insufficiently reliable.

I agree with defendant, however, that Dr. Ostergard may not testify that defendant's products are likely to cause plaintiff future injuries attributable to degradation of her mesh implant or to the ongoing presence of mesh in her body, as Dr. Ostergard acknowledged that there is no evidence of either in her medical records. *See* Ostergard Dep., ECF 124-2 at 66-68 (acknowledging that "there is nothing in...the medical records of this patient to indicate that degradation has occurred," nor "any indication in the records that the entire Restorelle mesh device was not removed"). *See Leavitt v. Ethicon, Inc.*, No. 2:20-CV-00176, 2021 WL 3674067, at *2 (D. Vt. Aug. 19, 2021) (excluding Dr. Ostergard's opinions concerning mesh degradation and risk of future injury

because they were "not case-specific and...not helpful in evaluating the risks Plaintiff...is reasonably likely to face in the future"). For similar reasons, Dr. Ostergard may not testify about polypropylene's general propensity to degrade in vivo or about injuries he believes such degradation can cause.

Bilal Chughtai

Plaintiff has disclosed Dr. Chughtai, a urologist specializing in Female Pelvic Medicine and Reconstructive Surgery, and an Associate Professor in the Department of Obstetrics and Gynecology at Weill Cornell Medicine, to testify "about the cause, nature and extent of injuries suffered by Ms. Teran because of defendant's pelvic mesh and the need for its removal." Pl.'s Resp., ECF 141, at 1. Dr. Chughtai's opinions in this connection are stated in a single paragraph of his seventeen-page report, the bulk of which—pages four through sixteen—is devoted to a list of Dr. Chughtai's extensive publications in the fields of urology, gynecology, and pelvic surgery. (Pages one through three of his report comprise a brief introduction and a summary of plaintiff's medical history drawn from the records Dr. Chughtai reviewed.)

The substance of Dr. Chughtai's opinion is set forth in the following excerpt:

> Dr. Chughtai will testify, to a reasonable degree of medical certainty, that Nidia Teran's continuing symptoms are most probably related to her initial mesh surgery and subsequent removal. The subsequent surgical intervention was necessary because of pelvic pain and

> incontinence. It is probable that the multiple procedures and the complex nature of mesh removal are the causes of Ms. Teran's chronic lower urinary tract symptoms, multiple surgical interventions, and continued pelvic pain.

Chughtai Rep., ECF 141-6 at 8. This opinion—which offers no analysis or discussion of any particular element of plaintiff's complex medical history, nor does it address the role any aspect of that history may have played in her injuries or ongoing symptoms—is a classic example of expert *ipse dixit*. As the Seventh Circuit has often reiterated, an expert "cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method[.]" *Clark v. Takata Corp.*, 192 F.3d 750, 759 (7th Cir. 1999). Nor can an expert offer merely a bottom line, as doing so supplies nothing of value to the judicial process. *Burns v. The Sherwin Williams Company*, No. 19-CV-5258, 2022 WL 4329417, at *26 (N.D. Ill. Sept. 18, 2022). Dr. Chughtai's one-paragraph statement of his opinions putatively based on the totality of records he reviewed offers just this type of unhelpful "bottom line."

In response to defendant's observation that Dr. Chughtai's opinions are not based on any discernable methodology, plaintiff points to his qualifications and suggests that because Dr. Chughtai "based his opinions on the medical records of the treating physicians, all of which include detailed descriptions of plaintiff's prior medical history," his approach amounts to a

reliable differential diagnosis. Pl.'s Resp., ECF 141 at 9. But that is plainly wrong: to conduct a valid differential diagnosis, "an expert must systematically 'rule in' and 'rule out' potential causes in arriving at her ultimate conclusion." *Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 705 (7th Cir. 2015). *See also James v. Coloplast Corp. & Coloplast Manufacturing US, LLC*, No. CV 20-654 (JRT/TNL), 2022 WL 4465956, at *5 (D. Minn. Sept. 26, 2022) (excluding expert opinion as *ipse dixit* based on expert's failure to "delineat[e] **any** connections between his causation opinion and the records he purports to have reviewed") (emphasis in original). Because there is no evidence that Dr. Chughtai "ruled in" or "ruled out" any of the potential alternative causes documented in her extensive medical history, his testimony does not satisfy *Daubert* standards and will be excluded.

The upshot of the foregoing discussion is that defendant is not entitled to summary judgment of plaintiff's claims in their entirety on the ground that she lacks admissible expert evidence of causation. Although plaintiff may not call Dr. Chughtai to testify, she may offer at least the testimony of Dr. Ostergard to support her causation theory.[4]

[4] I say "at least" because plaintiff asserts that the post-operative reports of her treating physicians also include evidence of causation. While treating physicians may offer opinion testimony only if they are properly disclosed as witnesses, defendant has not argued that plaintiff may not rely on the additional evidence to which she points.

Barring global judgment in its favor for lack of evidence that plaintiff's Restorelle Y mesh caused any of her injuries, defendant offers a host of arguments for summary judgment as to each of plaintiff's individual claims. I resolve these as set forth below.

B. Products Liability

"An injured plaintiff may allege one of two types of products liability claims: a strict liability claim or a negligence claim." *Africano v. Atrium Med. Corp.*, No. 17-CV-7238, 2021 WL 2375994, at *6 (N.D. Ill. June 10, 2021) (quoting *Salerno v. Innovative Surveillance Tech., Inc.*, 402 Ill. App. 3d 490, 497, 932 N.E.2d 101, 108 (1st Dist. 2010)). "The key distinction between the two types of claims lies in the concept of fault. In a strict liability claim, the focus of the inquiry is on the condition of the product itself. A negligence claim accounts for a defendant's fault as well as the product's condition." *Id.* Both theories require evidence of proximate causation. *Thornton v. M7 Aerospace LP*, 796 F.3d 757, 770 (7th Cir. 2015) ("[u]nder Illinois law, in a products liability action, whether based on strict liability or negligence, the plaintiff must demonstrate a causal relationship between the injury and the manufacturer's product."). *See also Salerno*, 932 N.E. 2d at 109, 111 (identifying proximate causation as an element under each standard).

The Supreme Court of Illinois "has recognized three theories of strict product liability: manufacturing defect, design defect, and failure to warn." *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 348 (Ill. 2008), opinion modified on denial of reh'g (Dec. 18, 2008).

Design Defect

As evidence of a design defect, plaintiff points to the testimony of Dr. Sondra Summers, the gynecologist who performed her hysterectomy, who testified that during the procedure, she observed that the mesh was "kind of balled up" and "encased in scar tissue." Summers Dep., ECF 146-6 at 130. In Dr. Ostergard's view, the "balled up" condition of the mesh is the result of its tendency to shrink or contract—a defect that he opines makes it "unreasonably dangerous," an element plaintiff must establish to prevail on her claim. *Mikolajczyk* 901 N.E.2d at 345.

Defendant argues that plaintiff has not raised a triable issue as to this element under what is known as the "risk-utility" test, one of two approaches Illinois courts use to determine whether a product is unreasonably dangerous. *See Bensenberg v. FCA US LLC*, 31 F.4th 529, 535 (7th Cir. 2022). In defendant's view, Dr. Chughtai's deposition testimony referring to POP repair using polypropylene mesh as the "gold standard" and stating that he would use Coloplast mesh if it were stocked at the hospital at which he were performing surgery, and Dr. Sadah's testimony that

he continues to use Restorelle Y mesh, undermine any argument that the risks of Restorelle Y outweigh its utility. But defendant fails to explain why this testimony disposes of the risk-utility analysis. Even assuming Dr. Chughtai's testimony were not excluded, plaintiff is entitled to have a jury weigh whatever inferences it might draw from his and Dr. Sadah's statements against evidence such as Dr. Ostergard's testimony concerning the physical properties of the mesh and its tendency to shrink or contract, both of which, he opines, render the product unreasonably dangerous.[5]

Defendant's sweeping assertion that plaintiff has "failed to offer any evidence or expert testimony that any purported design defect was a cause" of her injuries is incorrect. This argument presumably rests on the assumption that Dr. Ostergard's causation opinions will be excluded. Having denied this aspect of

[5] I am mindful of defendant's objection to Dr. Ostergard's testimony concerning the pore size of the mesh based on his "visual inspection." While I agree that visual inspection is not a reliable method for determining the size of pores that are measured in microns, it seems to me that the more important question is not the size of the mesh's pores prior to implantation, but rather whether the mesh's design allowed for shrinkage or contracture post-operatively in a way that made the mesh unreasonably dangerous. There is no dispute that Dr. Ostergard cited studies showing that polypropylene mesh in general is subject to shrinkage. The fact that these studies were not performed on Restorelle mesh specifically goes to the weight, not the reliability, of Dr. Ostergard's testimony, and a jury could construe Dr. Summers's observation that plaintiff's mesh was "balled up" as evidence that the product at issue here in fact contracted in vivo.

defendant's *Daubert* motion targeting Dr. Ostergard's opinions, I need not address defendant's argument further. I deny defendant's summary judgment motion to the extent it targets plaintiff's design defect claim.

Failure to Warn

Defendant raises several arguments in connection with plaintiff's failure to warn claim, but one is dispositive: Plaintiff offers no evidence to establish, as she must, that inadequate warnings played any causal role in her injuries. *See Vaughn v. Ethicon, Inc.*, No. 20-CV-562-JPG, 2020 WL 5816740, at *4 (S.D. Ill. Sept. 30, 2020) ("[u]nder Illinois law, a plaintiff must show 'that the presence of adequate warnings would have prevented the plaintiff's injuries.'" (quoting *Broussard v. Houdaille Indus., Inc.*, 539 N.E.2d 360, 363 (Ill. App. Ct. 1989)). Indeed, plaintiff acknowledges that she relied entirely on Dr. Sadah's advice when deciding to receive the Restorelle Y mesh implant, and there is no evidence that Dr. Sadah read or relied upon the Instructions For Use ("IFU") accompanying the Restorelle Y mesh when formulating his recommendation. Asked at his deposition whether he "rel[ied] on" the IFU that accompanied the mesh he implanted in plaintiff,[6] Dr. Sadah provided this answer:

[6] Actually the question was, "Did you rely on the Instructions For Use that accompanied the Altis sling?" ECF 146-3 at 99:17-19, but Dr. Sadah testified that his answer would be the same for the IFU accompanying the Restorelle Y. *Id.* at 101:4-7.

> So this was not my first to-do so, I mean, initially when I embark on doing something for the first time, whether it's a new instrument, whether it's a new device, whether it's a new implant, including mesh of course, I will be informed about it. Either I would have read about it or I would have attended a course about it or whether it's a technique that we have to learn more the -- if you will, the basic science of how that material works as it compares to other competitor ones. In addition, the rep, when he or she brings the item for a first time, will essentially give everyone sort of an in-service information, not just -- not so much to me but also to the staff, intraoperatively how to process that mesh, how it's handled and so forth, so that if they do drop it on the floor, they have a replacement, et cetera. So once that takes place the first time, we don't go through that as a routine.

Sadah Dep., ECF 146-3 at 99-100. *See also* Pl.'s Resp. to Def.'s L.R. 56.1 Statement, ECF 146 at ¶ 10 (admitting that "Dr. Sadah relied on his training, experience, and guidance from his colleagues and peers to inform his decision to use the Restorelle Y, including using Restorelle Y to treat in March 2014."). In short, the evidence shows that Dr. Sadah learned about the product and how to use it from various sources, but none of them was the IFU.

Moreover, plaintiff acknowledges that Dr. Sadah continued to perform surgeries using Restorelle Y even after he learned of her injuries, and that he continued to consider sacrocolpopexy surgery with mesh as the "gold standard" for treating POP. ECF 146 at ¶¶ 13-14. These admissions foil any inference that different warnings alerting Dr. Sadah to the specific risks that ultimately materialized in plaintiff's case would have caused him not to use

the product. Meanwhile, plaintiff never saw the Restorelle Y IFU herself, nor did she see marketing materials or other representations by Coloplast about the product. Pl.'s Resp. to Def.'s L.R. 56.1 Statement, ECF 146 at ¶¶ 16-17. On these facts, I need not resolve the parties' dispute over the role of the "learned intermediary" doctrine; since neither plaintiff nor Dr. Sadah read or relied upon the IFU, no reasonable jury could conclude that different warnings might have prevented plaintiff's injuries.[7] *See Aquino v. C.R. Bard, Inc.*, 413 F. Supp. 3d 770, 790 (N.D. Ill. 2019) (to prevail on failure to warn claim under Illinois law, plaintiff "must allege that if there had been a proper warning, her surgeon would have declined to use the product") (citing *In re Zimmer, NexGen Knee Implant Prod. Liab. Litig.*, 884 F.3d 746, 752 (7th Cir. 2018) ("[a] plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would

[7] Indeed, plaintiff's insistence that the doctrine "does not apply" in this case, Pl.'s SJ Resp., ECF 147 at 7, 10, does not advance her argument. If the doctrine is inapplicable, that means only that defendant cannot stand on adequate warnings to plaintiff's surgeon as a defense to the argument that defendant breached its duty to warn her. *See Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 951 (Ariz. 2016) ("the doctrine provides a means by which a manufacturer may satisfy its duty to warn the end user."). The shortcoming in plaintiff's evidence is one of causation. Regardless of whether the learned intermediary doctrine applies, plaintiff must offer some evidence to suggest that different, better warnings *to someone* would have prevented her injury. *See Aquino v. C.R. Bard, Inc.*, 413 F. Supp. 3d 770, 790 (N.D. Ill. 2019) The record contains no such evidence.

have altered behavior and avoided injury.") (Wisconsin law); *N. Tr. Co. v. Upjohn Co.*, 572 N.E.2d 1030, 1037 (Ill. App. 1991) (to prevail on failure to warn claim, "plaintiff was required to show that the omission of such information made the warning inadequate...and that this defect was the proximate cause of plaintiff's injuries."). For the foregoing reasons, defendant's motion for summary judgment is granted as to this claim.

Manufacturing Defect

Defendant is entitled to summary judgment of this claim as well, as plaintiff offers no evidence that her Restorelle Y mesh "depart[ed] from its intended design[.]" *Blue v. Env't Eng'g, Inc.*, 828 N.E.2d 1128, 1139 (Ill. 2005). "A manufacturing defect and design defect are '*different* theories of liability.'" *Africano v. Atrium Med. Corp.*, No. 17-CV-7238, 2021 WL 2375994, at *8 (N.D. Ill. June 10, 2021) (quoting *Salerno v. Innovative Surveillance Tech., Inc.*, 932 N.E.2d 101, 108 (Ill. App. 2010) (emphasis in *Africano*). As the *Salerno* court explained, "[a] manufacturing defect occurs when one unit in a product line is defective, whereas a design defect occurs when the specific unit conforms to the intended design but the intended design itself renders the product unreasonably dangerous." 932 N.E.2d at 108. Plaintiff's response brief suggests that she fails to perceive the difference between these two theories. For example, she points to Dr. Ostergard's testimony concerning "general defects in the weight of Restorelle

mesh, which vary from design parameters" and "deviations in mesh dimensional results, including its width" as evidence of a manufacturing defect. Pl.'s Resp., ECF 147 at 8. But what matters in connection with this theory of liability is the condition of plaintiff's "specific unit," and Dr. Ostergard concedes that neither he nor anyone else examined plaintiff's mesh to determine whether it conformed to the product's intended design. Without such evidence, plaintiff cannot proceed to trial on her claim of manufacturing defect.

C. Fraud-based Claims

Plaintiff fails to raise a triable issue on her fraud-based claims (common law fraud, fraudulent concealment, constructive fraud, and negligent misrepresentation) for substantially the reasons she cannot proceed on her failure to warn claim: She offers no evidence to suggest that she would not have gone forward with her implantation surgery if she (or Dr. Sadah) had been advised of the risks she faults defendant for omitting from the Restorelle Y IFU. In response to defendant's motion targeting her fraud-based claims, plaintiff reiterates the view that the learned intermediary doctrine does not bar these claims because the Restorelle Y IFU failed to "specify for any of the adverse events listed therein the expected time of onset, the anticipated duration of the event, the likely intensity of symptoms, or that the product could degrade after implantation." Pl.'s SJ Resp., ECF

147 at 9. But regardless of whether the learned intermediary doctrine applies, plaintiff points to nothing in the record to suggest that Dr. Sadah would not have recommended, or that she would not have consented to, implantation with Restorelle Y mesh if she had known the omitted information. *Cf. Corder v. Ethicon, Inc.*, 473 F. Supp. 3d 749, 758 (E.D. Ky. 2020) (acknowledging that plaintiff "has the burden on proximate cause, and any warning defect, to support relief, must have caused her injury," and concluding that the plaintiff's attestation that "if she were apprised of all alleged complications stemming from Defendants' products, she would not have elected implantation" raised a factual dispute precluding summary judgment of her fraud-based claims).

D. Negligent Infliction of Emotional Distress ("NIED")

Defendant argues that plaintiff's NIED claim fails because it requires proof of a physical injury proximately caused by defendant's negligence, and the record does not support a finding that the Restorelle Y mesh caused any of her injuries. This argument does not warrant summary judgment in light of my conclusion above that plaintiff has presented sufficient evidence to allow a jury to conclude that her injuries were proximately caused by the mesh's defective design. Nevertheless, plaintiff's response falls short of identifying evidence sufficient to raise a triable issue as to each element she must prove to prevail on

this claim. Plaintiff's four-line argument asserts that defendant's motion fails to address testimony in which she "identified the conditions she suffers and the impact that her injuries continue to have on her life." *See* Pl.'s SJ Resp., ECF 147 at 10. But the deposition testimony to which plaintiff points describes symptoms she experienced "before Dr. Sadah's surgery." Teran Dep., ECF 146-1 at 72:3-4. Nothing about that testimony suggests that she suffered emotional distress *as a result of* her implantation with defendant's mesh, much less does it support "the traditional elements of negligence: duty, breach, causation, and damages." *Schweihs v. Chase Home Fin.*, LLC, 77 N.E.3d 50, 58 (Ill. 2016) (identifying elements of NIED claim). For these reasons, defendant's motion is granted as to plaintiff's NIED claim.

E. Punitive Damages

Defendant seeks summary judgment with respect to plaintiff's claim for punitive damages on the ground that a request for punitive damages is "merely a type of remedy," rather than an independent claim. *Vincent v. Alden-Park Strathmoor, Inc.*, 948 N.E.2d 610, 615 (Ill. 2011). Defendant argues further that plaintiff cannot prove an entitlement to punitive damages, since she lacks evidence of the type of willful and wanton or outrageous conduct that would support such relief. While it may be that Illinois law does not treat a prayer for punitive damages as a "claim," the issue is academic, since plaintiff's ability to

recover punitive damages does not turn on how her request is characterized. Moreover, I am not persuaded that no reasonable jury could award punitive damages on the record here. Defendant's motion is denied in this respect.

F. Expert Testimony – Remaining Issues

Although not dispositive of defendant's summary judgment motion, resolution of issues raised in the parties' remaining *Daubert* motions will shape the course of proceedings as the parties head towards trial. Accordingly, I address these issues below.

Ostergard's Additional Opinions

In addition to Dr. Ostergard's causation opinions, which I addressed in a previous section, defendant seeks to limit various other aspects of his proposed testimony. Most saliently, defendant seeks to preclude Dr. Ostergard from testifying about "safer alternative designs" on the ground that what he really describes are alternative treatments or procedures, rather than alternative designs for the Restorelle Y device. It is true that some courts have barred this aspect of Dr. Ostergard's testimony on that ground. *See, e.g., Leavitt v. Ethicon, Inc.*, No. 2:20-CV-00176, 2021 WL 3674067, at *4 (D. Vt. Aug. 19, 2021) ("a safer alternative treatment or procedure that does not include a safer alternative design of the product in question yields no relevant information regarding whether a safer alternative design was feasible."); *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL

2327, 2017 WL 1264620, at *3 (S.D. W. Va. Mar. 29, 2017) (same). Other courts, however, have concluded that Dr. Ostergard's criticism of the materials or specifications used in the manufacture of vaginal mesh is admissible evidence of the existence of safer alternatives. *See Arruda v. C.R. Bard, Inc.*, No. 619CV1523TJMATB, 2020 WL 4569436, at *18 (N.D.N.Y. Aug. 6, 2020) ("Dr. Ostergard does not propose abandoning the sling device for some other procedure or treatment. He instead criticizes the material from which Defendant constructed the sling. He suggests that another material would be safer in serving the same function. That amounts to an argument for a safer alternative design, just as arguing that using aluminum instead of steel in a bike frame would make the frame stronger, lighter, and more durable, and thus safer."). Yet other courts have concluded that because alternative procedures may be relevant, for example, to rebut a defendant's claim that surgical repair using its product was the "gold standard" for treatment of a plaintiff's condition—an argument defendant appears poised to make in this case—the admissibility of opinions concerning such alternatives is best decided at trial. *See, e.g., McBroom v. Ethicon, Inc.*, No. CV-20-02127-PHX-DGC, 2021 WL 2709292, at *19 (D. Ariz. July 1, 2021); *Heinrich v. Ethicon, Inc.*, No. 220CV00166APGVCF, 2021 WL 2290996, at *3 (D. Nev. June 4, 2021). This last course strikes me as sensible, so I deny defendant's motion in this respect.

To the extent plaintiff intends to solicit testimony from Dr. Ostergard concerning defendant's corporate knowledge or state of mind, however, I agree that such opinions are not appropriate subjects of expert testimony. *See Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *3 (S.D.W. Va. Feb. 7, 2015) ("[a]lthough an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.").

Lastly, Dr. Ostergard will not be permitted to testify about informed consent or the adequacy of the Restorelle Y IFU because his opinions on these questions are relevant, if at all, to plaintiff's failure to warn claim, which is no longer at issue.

Jimmy W. Mays

Plaintiff has designated Dr. Mays, Distinguished Professor of Chemistry at the University of Tennessee, as an expert to offer opinions concerning the suitability of defendant's polypropylene mesh products for permanent implantation in the human body. Specifically, Dr. Mays opines that defendant's products are susceptible to degradation *in vivo*, and that such degradation causes adverse effects on the human body. The parties hotly dispute

the reliability of Dr. Mays's opinions, and indeed, courts around the country have considered the question in a number of suits in this MDL and have come to varying conclusion. *Compare*, e.g., *Nunez v. Coloplast Corp.*, No. 19-CV-24000, 2020 WL 2315077, at *4 (S.D. Fla. May 11, 2020) (denying motion to exclude Mays's testimony); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 538 (S.D.W. Va. 2014), as amended (Oct. 29, 2014) (permitting Dr. Mays "to testify generally about polypropylene degradation based on his experience and review of the literature"); and *Cantrell v. Coloplast Corp.*, No. 20-CV-0672 (WMW/JFD), 2022 WL 2806390, at *4 (D. Minn. July 18, 2022) (allowing Dr. Mays to testify "as to the general process of mesh degradation" but excluding as unreliable his opinions "about the specific properties of Coloplast's mesh"), *with Martinez v. Coloplast Corp. & Coloplast Mfg. US, LLC*, No. 2:18-CV-220, 2022 WL 409638, at *4 (N.D. Ind. Feb. 10, 2022) (finding that Dr. Mays failed to "apply the same 'intellectual rigor' to his litigation opinions as he did to his 400 published articles" and excluding his opinions in their entirety).

Ultimately, however, this case does not compel me to take sides on the reliability of Dr. Mays's methodology, since his opinions about polypropylene's tendency to degrade have no place in this case. As noted above, there is no evidence that plaintiff's mesh degraded, or that any of her injuries was caused by mesh degradation. For that reason, Dr. Mays's opinions are more likely

to confuse than to help the jury decide the issues before it. His testimony will be excluded. *See Hammock v. Coloplast Corp.* et. al, No. 3:19-cv-01041-RJD, at 3 (S.D. Ill. Mar. 29, 2021) (slip op.) (declining to interpret evidence that the defendant's product "rolled on itself" to mean that the product "degraded" and excluding Dr. Mays's opinions as irrelevant as they concerned oxidative degradation).

Emily Cole

Dr. Cole is another repeat player in this MDL, and the admissibility of her opinions regarding the safety and design of mesh products used to repair POP and SUI, including Restorelle Y, has been considered by several courts. *See Martinez v. Coloplast Corp. & Coloplast Mfg. US, LLC*, No. 2:18-CV-220, 2022 WL 444281 (N.D. Ind. Feb. 14, 2022) (denying motion to exclude Dr. Cole's opinions); *Nunez v. Coloplast Corp.*, No. 19-CV-24000, 2020 WL 2315077, at *5 (S.D. Fla. May 11, 2020) (same); *Bayless v. Bos. Sci. Corp., No.* 620CV831ORL37GJK, 2020 WL 10058191, at *6 (M.D. Fla. Dec. 7, 2020) (permitting Dr. Cole to testify "as to what she found in the literature regarding mesh outcomes—and whether those findings are consistent with her own clinical experience" but precluding her from testifying "that her experiences are representative of all clinical experiences (outside of a discussion of the scientific literature) or that the product is or is not defective, whether its physical properties change in

vivo, or other aspects of the mesh's material properties that go beyond her clinical experience and her expertise as a medical doctor.").

Dr. Cole's qualifications are beyond reasonable dispute. As the *Martinez* court recently observed:

> Dr. Cole is clearly an experienced female pelvic health surgeon. She has performed over 1,500 pelvic floor surgeries in the last ten years, with five involving Restorelle Y. She currently serves as the Chief Urologist and Director of the Female Pelvic Health Center at Sharp Ress-Stealy Medical Group where she maintains an active surgical practice that specializes in using mesh implants to treat female POP and urinary incontinence conditions.

Martinez 2022 WL 444281, at *3. Nothing in plaintiff's motion provides a reason to doubt Dr. Cole's ability to testify competently about the safety and design of Restorelle Y mesh.

As for the reliability of the specific opinions she proposes to offer in this case—which, in short, are that: 1) all pelvic-floor surgeries have risks and benefits, and that Restorelle Y should not be deemed defective based on adverse outcomes experienced by certain patients; and 2) the medical literature and her personal experience indicate that Restorelle Y is safe and effective for implantation in appropriately selected patients—I conclude that her methodology of observing complication rates in her own practice and reviewing relevant medical literature provides a sound basis for her conclusions. *See* Cole Rep., ECF 113-1 at 12. Plaintiff's argument that Dr. Cole cannot opine that

the Restorelle Y mesh is not defective because she is not an expert in "how a company designs medical devices" and has not "assisted with the design [of] any medical products" is misplaced. Dr. Cole does not purport to offer opinions about the design *process*. Instead, she describes certain of the product's design features and offers opinions about its functionality and safety based on outcomes she has observed personally and has reviewed in the literature. Because I am satisfied that Dr. Cole's methodology satisfies *Daubert* standards, plaintiff's motion to preclude her testimony is denied.[8]

Patrick Culligan

Dr. Culligan is a urogynecologist who is board certified both in General Obstetrics and Gynecology and in Female Pelvic Medicine and Reconstructive Pelvic Surgery. Defendant has designated Dr. Culligan to offer causation opinions related to polypropylene products generally and defendant's Restorelle Y mesh in particular. Plaintiff moves to exclude various aspects of Dr. Culligan's testimony, including his opinions about Dr. Sadah's surgical technique and his testimony concerning mesh shrinkage and degradation. Plaintiff also seeks to preclude Dr. Culligan from

[8] I note that plaintiff filed no reply in support of her motion, which may indicate that she concedes defendant's arguments in response to her motion.

offering opinions about "the FDA or regulatory issues." Mot., ECF 123 at 4.

Having reviewed the parties' motions and accompanying materials, I conclude first that Dr. Culligan may testify to his opinion that Dr. Sadah's surgical technique was "unconventional," as that testimony is not based exclusively on his own experience, as plaintiff asserts, but also on his "rather extensive knowledge of the field of urogynecology," which includes researching and teaching in the field of pelvic reconstructive surgery. *See generally* Culligan CV, ECF 140-7.

As for Dr. Culligan's opinions concerning mesh shrinkage, plaintiff argues that his opinions are unreliable because they "ignore contrary studies." Pl.'s Mem., ECF 123 at 3. Defendant disputes the factual basis for this argument, pointing to the wide body of literature Dr. Culligan cites. At all events, however, plaintiff will have ample opportunity at trial to cross-examine Dr. Culligan concerning the studies she believes he failed to consider. Accordingly, her motion is denied insofar as it relates to Dr. Culligan's opinions about mesh shrinkage. For reasons explained elsewhere in this opinion, however, Dr. Culligan will not be permitted to testify about mesh degradation.

To the extent plaintiff challenges Dr. Culligan's opinions concerning defendant's compliance with FDA regulatory processes, her motion is granted. Judge Goodwin, who presided over the MDL

in which this case originated, has "repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process," and has consistently excluded expert testimony on the subject because "the 510(k) process does not relate to safety or efficacy." *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 725 (S.D.W. Va. 2014) (citing cases). The Seventh Circuit agrees. *See Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1018 (7th Cir. 2020) (concluding that because "§ 510(k) clearance is remote from FDA safety review," evidence of the clearance process was only minimally probative of product safety and probative value was outweighed by likelihood of prejudice). Because I see no compelling basis for departing from these rulings, Dr. Culligan will not be permitted to testify about FDA regulatory processes, regardless of whether he is qualified to do so.

Karen Becker

For similar reasons, and consistently with other courts that have considered the admissibility of her opinions on the subject, I grant plaintiff's motion to exclude the testimony of Karen Becker concerning medical device industry practices and the FDA's regulation of medical devices. *See, e.g., Martinez v. Coloplast Corp.*, No. 2:18-CV-220, 2022 WL 571398, at *1 (N.D. Ind. Feb. 23, 2022) (excluding "Dr. Becker's opinions regarding the FDA in general as well as its regulatory process as it pertains to labeling, adverse event reporting system, and the § 510(k)

clearance process."); *Wood v. Am. Med. Sys. Inc.*, No. 120CV00441DDDKLM, 2021 WL 1178547, at *3 (D. Colo. Mar. 26, 2021) (same). Additionally, to the extent Dr. Becker's testimony addresses FDA regulation of product labeling, her testimony is irrelevant given that I have granted summary judgment on plaintiff's failure to warn claim.

Diana Molavi

Defendant offers the opinions of Dr. Molavi, a board-certified anatomic and clinical pathologist who serves as Chief of Pathology at Sinai Hospital in Baltimore, Maryland, to rebut the causation opinions offered by Drs. Ostergard and Chughtai. The opinions she articulates concern the human body's response to polypropylene mesh, the limited value of existing studies of the pathologic response to mesh, and the limitations of histologic examinations. Plaintiff asserts that Dr. Molavi "is not qualified to testify regarding the ability of polypropylene mesh to cause pain in patients," and that her methodology is unreliable because she "fails to use any scientific method" in reaching her conclusions. These arguments do not survive scrutiny.

As to the first, I agree with the observation of the court in *Nunez v. Coloplast Corp.*, No. 19-CV-24000, 2020 WL 2315077, at *5 (S.D. Fla. May 11, 2020), that "no serious argument can be made

about Dr. Molavi's qualifications."[9] In addition to the credentials mentioned above, Dr. Molavi "is the author of an academic textbook on the topic of surgical pathology, the diagnostic process, and female anatomy [and] has numerous peer-reviewed articles" in the relevant field. *Id.* Having reviewed her CV and deposition testimony, I find that Dr. Molavi is amply qualified "to assess and interpret scientific literature that analyzes whether histopathology findings (such as the presence of macrophages, foreign body giant cells, fibrosis or chronic inflammation) correlate with a patient's reported symptoms, including pain, following surgery with polypropylene surgical mesh." Def.'s Resp., ECF 137 at 6.

As to the reliability of Dr. Molavi's opinions, plaintiff suggests that because she has not performed independent "research on how transvaginal mesh implants react in the human body," her conclusions are not the product of "a reliable scientific method." Pl.'s Mem. ECF 115 at 4. But independent research is not the only means of arriving at scientifically reliable opinions. As Dr. Molavi explained in her deposition, a microscope is a

[9] I am mindful that the *Nunez* court went on to exclude Dr. Molavi's testimony on the ground that her own deposition testimony called into question the reliability of her opinions. For reasons explained below, I conclude that the opinions she offers in this case are based on a reliable methodology, and that plaintiff may address the deposition testimony that "bothered" the *Nunez* court through cross-examination. *Nunez*, 2020 WL 2315077, at *6.

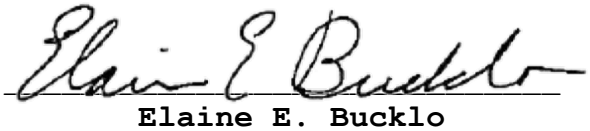
pathologist's "tool" for evaluating the human body's response to the presence of a foreign body such as polypropylene mesh, and she analyzes thousands of histological slides through a microscope each year. Molavi Dep., ECF 137-20 at 104, 22. ECF. Dr. Molavi's report addresses the tissue responses she expects to see, based on her twelve years of experience, when polypropylene mesh is present. She then addresses the scientific literature concerning the relationship between those responses and patient symptoms and concludes that "there is poor correlation between symptoms and pathology." I am satisfied that Dr. Molavi's approach is appropriately grounded in the tools and methods of her profession. Plaintiff's objection that she "ignored" literature that does not support her conclusions is, as I noted above in conjunction with my analysis of Dr. Culligan's testimony, a criticism that is best evaluated through cross-examination.

III.

For the foregoing reasons, I grant defendant's motion for summary judgment with respect to plaintiff's claims of strict liability-manufacturing defect (Count II), strict liability – failure to warn (Count III), common law fraud (Count VI), fraudulent concealment (Count VII), constructive fraud (Count VIII), negligent misrepresentation (Count IX), and negligent infliction of emotional distress (Count X) only. In addition, I grant defendant's motions to exclude the testimony of Drs. Bilal

Chughtai and Jimmy Mays, and I grant plaintiff's motion to exclude the testimony of Dr. Karen Becker. I deny plaintiff's motions to exclude the testimony of Drs. Emily Cole and Diana Molavi. Finally, I grant in part and deny in part defendant's motion to preclude the testimony of Dr. Ostergard and plaintiff's motion to preclude the testimony of Dr. Culligan.

ENTER ORDER:



Elaine E. Bucklo
United States District Judge

Dated: September 30, 2022